APR 7 2006

510(k) Summary
Vectra™ Laser System and Accessories

K060114

Submitter's Name:	Xintec Corporation, dba, Convergent Laser Technologies, 1660 S. Loop Road Alameda, CA 94502
Phone Number:	510-832-2130
Fax Number:	510-832-1600
Contact Person:	Marilyn M. Chou, Ph.D.
Date Prepared:	February 23, 2006
Name of Device:	Vectra™ Laser System and Accessories
Sponsor:	Xintec Corporation, dba, Convergent Laser Technologies, 1660 S. Loop Road Alameda, CA 94502
Classification:	Diode laser
Predicate Device:	Ceralas Diode 980 nm Laser System (Model 100)

Intended Use/Indications for Use:
The device is intended for delivery of laser light to soft tissue in the contact and non-contact mode during surgical procedures including via endoscope. The device is generally indicated for use in incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose, and throat and oral surgery (otolaryngology), arthroscopy, gastroenterology, neurosurgery (peripheral nervous system), pulmonary and cardiothoracic surgery, dental applications, and endovenous occlusion of the greater saphenous vein.

The device is specifically indicated for use as follows:

Ear, Nose and Throat and Oral Surgery (Otolaryngology)

Hemostasis, incision, excision, ablation, coagulation and vaporization of tissue from the ear, nose, throat and adjacent areas including soft tissue in the oral cavity. Examples include:

Removal of benign lesions from the ear, nose and throat

Excision and vaporization of vocal cord nodules and polyps

Incision and excision of carcinoma in situ
Ablation and vaporization of hyperkeratosis
Excision of carcinoma of the larynx
Laryngeal papillomectomy
Excision and vaporization of herpes simplex I and II
Neck dissection

Arthroscopy

Hemostasis, incision, excision, coagulation, vaporization and ablation of joint tissues during arthroscopic surgery. Examples include:

Menisectomy
Synovectomy
Chondromalacia

Gastroenterology

Hemostasis, incision, excision, ablation, coagulation and vaporization of tissue in the upper and lower gastrointestinal tracts an also with endoscopic procedures. Examples include:

Hemostasis of upper and lower GI bleeding
Excision and vaporization of colorectal carcinoma
Excision of polyps

General Surgery, Dermatology, Plastic Surgery and Podiatry

Excision, ablation, vaporization and photocoagulation of skin lesions, hemostasis, incision, excision, vaporization, ablation and debulking of soft tissue, abdominal, rectal, skin, fat or muscle tissue and dermabrasion. Examples include:

Matrixectomy
Excision of neuromas
Excision of periungual and subungual warts
Excision of plantar warts
Excision of keloids
Liver resection
Excision of cutaneous lesions
Hemorrhoidectomy
Appendectomy
Debridement of decubitus ulcers
Hepatobiliary tumors
Mastectomy
Dermabrasion
Vaporization and hemostasis of capillary hemangioma
Excision, vaporization and hemostasis of abdominal tumors
Excision, vaporization and hemostasis of rectal pathology
Pilonidal cystectomy
Herniorapphy
Adhesiolysis

Parathyroidectomy
Laparoscopic cholecystectomy
Thyroidectomy
Resection of organs
Debridement of wounds
Photocoagulation of teleangectasia of the legs and face
Photocoagulation of vascular lesions of the face and extremities
Endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux
Treatment of reticular veins and branch varicosities

Urology

Excision, vaporization, incision, coagulation, ablation and homeostasis of urological, including BPH/prostatic, tissues. Examples include:

Vaporization of uretheral tumors
Release of urethral stricture
Removal of bladder neck obstruction
Excision and vaporization of condyloma
Lesions of external genitalia

Gynecology

Ablation, excision, incision, coagulation, hemostasis and vaporization of gynechological tissue. Examples include:

Endometrial ablation
Excision or vaporization of condylomata acuminate
Vaporization of cervical intraepithelial neoplasia
Cervical conization
Menorrhagia

Neurosurgery

Vaporization, coagulation, excision, incision, ablation and hemostasis of soft tissue. Examples include:

Hemeostasis in conjunction with menigiomas

Cardiac Surgery

Hemostasis and coagulation of soft tissue, including cardiac tissue

Pulmonary Surgery

Hemostasis, vaporization, coagulation, incision, excision and ablation of soft tissue in the pulmonary system. Examples include:

Tracheobronchial malignancy or stricture
Benign and malignant pulmonary obstruction
Endoscopic pulmonary applications

Dental Applications

Indicated for the following applications on intraoral and extraoral soft tissue (including marginal and interdental gingival and epithelial lining of free gingival): frenectomy, frenotomy, biopsy, operculectomy, implant recovery, gingivectomy, gingivoplasty, gingival troughing, crown lengthening, hemostasis of donor site, removal of granulation tissue, laser assisted flap surgery, debridement of diseased epithelial lining, incisions and draining of abscesses, tissue retraction for impressions, papillectomy, vestibulopasty, excision of lesions, exposure of unerupted/partially erupted teeth, leukoplakia, removal of hyperplastic tissues, treatment of aphthous ulcers and sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket), pulpotomy, pulpotomy as an adjunct to root canal therapy and light activation of bleaching materials for teeth whitening.

Endovenous Occlusion of the Greater Saphenous Vein in Patients with Superficial Vein Reflux

Indicated for use in the endovascular coagulation of the Greater Saphenous Vein (GSV) of the thigh in patients with Superficial Vein Reflux.

Technical Characteristics

The Vectra™ Laser System and Accessories is substantially equivalent to the Optica and Odyssey Laser Systems (Xintec Corporation, dba, Convergent Laser Technologies, Alameda, CA) and Ceralas D 980 Diode Laser Systems (East Longmeadow, MA)) previously cleared for marketing under applicable 510(k) pre-market notification regulations.

Table I summarizes device specifications of the Vectra Laser Systems compared to the Xintec Corporation Optica and Odyssey Laser Systems (Xintec Corporation, dba, Convergent Laser Technologies, Alameda, CA) and Ceralas D 980 Diode Laser System (East Longmeadow, MA)) which have been previously cleared for marketing under applicable 510(k) pre-market notification regulations.

Table I: DEVICE DESCRIPTION AND EQUIVALENCE INFORMATION

Specifications

	Vectra™	Optica™ 510K# K901710	Odyssey™ 510K# 951910	Ceralas 510L#K050824
Wavelength	980nm± 10%	1064nm± 10%	2100nm± 10%	980nm
Maximum Output Power	10/20/30W; 60W; 80W; 100W; 120W	60W; 80W; 100W; 120W	15W; 30W; 45W; 60W; 80W	15W; 25W; 50W; 100W

Operating Modes	Continuous or pulsed	Quasi-Pulsed	Pulse	Continuous or pulsed
Aiming Beam	Green	Red	Green	Red
Laser Activation	Footswitch	Footswitch	Footswitch	Footswitch
Cooling	Air-cooled	Air-cooled	Air-cooled	Air-cooled
Weight	~200 lbs	250 lbs	175 lbs	50 lbs
Power Requirement	110/220VAC	110/220VAC	110/220VAC	110/220VAC

Note: These prototype specifications are subject to modifications for the final production models.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 7 2006

Xintec Corporation, dba
Convergent Laser Technologies
c/o Marilyn M. Chou, Ph.D.
1660 South Loop Road
Alameda, California 94502

Re: K060114
Trade/Device Name: Vectra™ Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: February 23, 2006
Received: February 24, 2006

Dear Dr. Chou:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K#060114**

Device Name: **Vectra™ Laser System**

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Division of General, Restorative, and Neurological Devices

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Excision of periungual and subungual warts
Excision of plantar warts
Excision of keloids
Liver resection
Excision of cutaneous lesions
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Appendectomy
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Menorrhagia

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Division of General, Restorative, and Neurological Devices[2]

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Neurosurgery

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

EC Mac

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Division of General, Restorative, and Neurological Devices

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